Health effects of eel consumption

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41358

Source
ToetsingOnline

Brief title
Fishermen study

Condition

- Other condition

Synonym
Not applicable

Health condition

Deze studie heeft niet direct betrekking op een aandoening.

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DNA methylation, Health effects, Persistent organic pollutants

Outcome measures

Primary outcome

The primary study outcome is the difference in serum POP concentrations in two groups of Dutch men consuming eel, namely the men consuming eel from polluted areas ('high* exposed) and those men consuming eel from clean areas (*low* exposed).

Secondary outcome

The secondary study outcomes are concentrations of thyroid hormones, retinol, insulin, glucose, cholesterol HDL, haematocrit, platelet count, testosterone and parameters for liver toxicity. In isolated peripheral blood mononuclear cells (PBMCs), DNA methylation patterns will be assessed. When a relationship between POP concentrations and DNA methylation is found, we will also measure gene expression levels.

Study description

Background summary

Seafood is considered to be beneficial for human health, but fish consumption also contributes to increased plasma levels of persistent organic pollutants (POPs). In the Biesbosch area eel fishing is prohibited since 2011. Before 2011, eel caught in this area was consumed for years, while the POP levels in eel were above the European legal limit. POPs degrade very slowly, and accumulate and cicrulate for years in exposed people. These pollutants are related to many adverse health effects, but it is not known whether negative health effects can be found in Dutch men consuming (polluted) eel every month. The mechanisms of action of POPs are not yet completely elucidated. This is difficult due to health effects that can occur long after exposure to these

compounds started. Earlier animal research showed that some health effects might be explained by epigenetic mechanisms. Changes in DNA methylation is an epigenetic mechanism that is known to be associated with various health effects. High concentrations of POPs have been associated with aberrant global DNA methylation in several epidemiological studies. As far as known, no research has been conducted to investigate the relationship between POP levels and gene-specific DNA methylation.

We hypothesize that men consuming eel from polluted areas have higher internal POP concentrations than men consuming eel from less polluted or clean areas. Furthermore, we hypothesize that internal POP concentrations are correlated to relevant biological outcomes, like hormone levels, and to aberrant DNA methylation.

Study objective

The main objective is to determine the difference in serum POP concentrations in two groups of Dutch men consuming eel, namely the men consuming eel from polluted areas ('high* exposed) and those men consuming eel from clean areas (*low* exposed).

The secondary objective is to correlate internal POP concentrations to biomarkers linked with health outcomes. Furthermore, we will try to correlate internal POP concentrations to gene-specific DNA methylation.

Study design

This is a cross-sectional study.

Study burden and risks

Subjects have to complete a short questionnaire, before they can enrol in this study. This will take approximately 15 minutes. Blood (±75 mL) will be withdrawn once by venipuncture in the arm of the volunteer. The risk of this is negligible and the burden is minimal. The subject*s length, body weight, and waist- and hip circumference will be assessed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male
Age between 40 and 70 years
Consumption of eel >= 1x per month

Exclusion criteria

There are no exclusion criteria.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2015
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-01-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46740.081.14